

REMARKS

As an initial matter, Applicants respectfully submit that claim 11 reads on the species elected in the response filed on January 28, 2008, and thus should not have been withdrawn from consideration in this action. Applicants respectfully request reinstatement of claim 11.

Upon entry of the instant amendment, claims 1, 3, 21-28, 31, 33-48 and 52-54 are pending in the instant application. Claim 32 is cancelled and Claims 52-54 are added. Support for the amendments may be found throughout the specification and claims, and particularly in FIGS. 1 and 3 and paragraphs 75-79 and 82. No new matter has been added, and all of the pending claims are consonant with the election of species made in the response of January 28, 2008.

Claims 1, 3, 21-28, 31 and 33-48 stand rejected. Claims 1, 3 and 21-28 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,036,071 to Marnay et al. (Marnay). Claims 31-48 are rejected under 35 U.S.C. 103(a) as being obvious over Marnay in view of U.S. Patent No. 6,368,350 to Erickson.

The rejection, as it may apply to the claims presented herein, is respectfully traversed.

Claim 1 is directed to a prosthetic spinal nucleus device for replacing the nucleus of a spinal disc and being implanted within the annulus. Claim 1 is amended to specify that the device is made up of two parts only and that the upper and lower shells each have a one-piece body. Claim 1 is further amended to specify that inner, arcuate bearing surfaces of the upper and lower shells are in sliding engagement with each other. Claim 1 is also amended to clarify that the smooth outer surfaces of the shell bodies extend continuously without interruption across the entire extent thereof between the ends and sides of the respective shell bodies. None of the relied upon art, either alone or in combination, discloses or suggests a two-part prosthetic spinal nucleus device including upper and lower shells having one-piece bodies with smooth outer surfaces extending continuously without interruption across the entire extent thereof between the

ends and sides of the shell bodies, or inner, arcuate bearing surfaces of the one-piece bodies of the shells that are in sliding engagement with one another as specified in amended claim 1.

More particularly, Marnay discloses a three-piece implant configured for total disc replacement, not a two-piece implant for replacing a nucleus of a spinal disc. Specifically, the implant of Marnay is provided with a central insert body 4 intended to be inserted between the upper and lower plates 2, 3 after the plates have been inserted into the intervertebral space. (See col. 5, lines 1-8). This is done so that the plates 2, 3 may be inserted in a low profile configuration to prevent excessive distraction of the vertebral joint during insertion. (See, e.g., col. 1, lines 52-55). In this regard, Marnay explicitly teaches structural features of the plates 2, 3 that cooperate to provide the low-profile insertion configuration. (See, e.g., col. 4, lines 25-32). However, in this configuration Marnay specifically contemplates insertion of the pivot insert 4 between the plates 2, 3 as otherwise the Marnay implant would not function as intended. When inserted, the central insert body 4 sits in between the upper and lower plates 2, 3 to provide the implant with its full height.

The shape and configuration of the Marnay device indicates that it is not configured for replacing a nucleus of the disc and for insertion in accordance with claim 1. Specifically, the protrusions 7, 15 and especially fins 6, 14 prevent the plates 2, 3 from being implanted within a natural annulus with the narrow ends of the plates 2, 3 leading the plates as they are inserted through an incision smaller than the elongated sides of the plates so that the natural annulus retains the plates in the intervertebral space. In particular, the extreme height of the fins 6, 14 would prevent the plates from being inserted through an incision smaller than the elongated sides of the plates. Instead of leading with the narrow ends, the plates 2, 3 of Marnay are inserted into the intervertebral space with the wider ends of the plates leading the plates in a direction parallel to the orientation of the fins 6, 14. (See col. 6, lines 32-47).

Further, the upper and lower plates have protrusions 6, 7, 14, and 15 “which serve the purpose of anchoring” the upper and lower plates 2, 3 to a vertebra. (See col. 3, lines 55-60). Thus, the plates 2, 3 do not have a smooth outer surface extending continuously without

interruption across the entire extent thereof between the ends and sides of the plates. Consequently, the plates can not slide with respect to the end plate or other adjacent tissue of the adjacent vertebrae. It is clear that Marnay does not intend for the corresponding outer surfaces 5 and 13 of the plates 2 and 3 to slide since Marnay also teaches surface roughening of the support faces for "optimal anchoring to the adjacent bone material." (See col. 5, lines 38-41).

Moreover, the plates 2, 3 of Marnay do not correspond with the upper and lower shell bodies of amended claim 1, because they lack inner, arcuate bearing surfaces that are in sliding engagement with one another. The upper plate 2 has a concave articulation surface 12, whereas the lower plate 3 has a flat central indentation 19, for receiving insert 4. (See FIG. 1). Thus, the lower plate lacks an inner arcuate bearing surface. The insert 4 cannot be construed to be part of the lower plate, because claim 1 requires that upper and lower shells have a one-piece body. Therefore, Marnay fails to disclose or suggest inner, arcuate bearing surfaces of the one-piece bodies.

For at least the reasons described above, Marnay clearly does not teach, disclose or suggest all of the limitations of independent claim 1. Therefore, Applicants respectfully submit that independent claim 1 is patentable over Marnay. It follows that claims 3, 11, 21-28 and 31, which depend cognately therefrom, are also allowable over Marnay for the reasons mentioned above. Additional distinctions over the cited art with respect to the dependent claims are described below.

Dependent claim 21 is dependent on claim 1 and further requires that one of the shells includes a gripping projection integral with the body of the one shell configured to allow a tool to grip around the projection for tool insertion of the shells through the annulus incision into the intervertebral space and shifting of the shells therein so that the narrow shell ends are not aligned with an insertion direction of the shells through the incision. The action cites leg 17 as a gripping projection that, along with bore 21 and pin-like extensions of a manipulation instrument, allow for tool insertion. Applicants respectfully submit that neither leg 17 alone, nor in combination with bore 21 and pin-like extensions of a manipulation instrument can be

considered a gripping projection. Leg 17 alone is not configured to allow a tool to grip around it. Marnay teaches that blind bores 20, 21 and 22, 23 serve as receptacles for pin-like extensions of a manipulation instrument. Thus, it is the bores 20, 21, 22, 23 that allow for tool insertion, and not the leg 17. However, a bore is not a gripping projection, at least because it does not "project" from anything and because it does not allow a tool to grip around itself. Further, the pin-like extensions can not form part of the gripping projection because the extensions are part of the insertion tool and not part of the implant itself as required in claim 21 reciting a gripping projection that is integral with the shell body. In addition, Marnay fails to disclose or suggest anything that allows shifting of the plates within the annulus so that the narrow ends are not aligned with an insertion direction of the shells through the incision. Thus, for the reasons mentioned with respect to claim 1 and for the immediately preceding reasons, Marnay clearly does not teach, disclose or suggest all of the limitations of dependent claim 21. Therefore, Applicants respectfully submit that dependent claim 21 is patentable over Marnay for these additional reasons.

Applicants also submit that amended dependent claim 22 is patentable over Marnay for the reasons stated with respect to claim 21 and because Marnay fails to teach, disclose or suggest a gripping post of at least one of the upper and lower shells that projects from the one shell toward the other of the upper and lower shells. Clearly, the bores 20-23 do not project from one shell toward the other, nor would pins inserted therein.

Claim 23 is believed to be patentable over Marnay for the reasons mentioned with respect to claim 21 and because Marnay fails to disclose or suggest a gripping projection including an arcuate engagement surface for rotating the one shell with a tool, and a generally flat abutment surface for locking the one shell against rotation with the tool. The Action cites pin-like extensions as providing the arcuate engagement surface. However, as mentioned above, the pin-like extensions are part of the tool and do not form part of the implant. Thus, they cannot be considered part of the gripping projection. Thus, Marnay clearly does not teach, disclose or

suggest all of the limitations of dependent claim 23. Therefore, Applicants respectfully submit that dependent claim 23 is patentable over Marnay for these additional reasons.

Claim 26 is believed to be patentable over Marnay because Marnay fails to disclose or suggest an integral gripping post projecting away from a flat surface portion of one of the shell bodies. The Action cites bore 20 as extending in leg 16. However, bore 20 cannot reasonably be construed as a gripping post that projects away from a flat surface portion. For instance, bore 20 is not a post, nor does it project from a flat surface portion. If bore 20 projected from a surface, it could not be considered a bore. In fact, a bore is exactly the opposite in structure from the recited gripping post. Thus, Marnay clearly does not teach, disclose or suggest all of the limitations of dependent claim 26. Therefore, Applicants respectfully submit that dependent claim 26 is patentable over Marnay for these additional reasons.

Claim 27 is also believed to be patentable over Marnay because Marnay fails to disclose or suggest a shell having a dome surface. Although insert 4 has a dome surface 25, insert 4 is not a shell, nor is it an integral part of either of the plates 2, 3. Thus, Marnay clearly does not teach, disclose or suggest all of the limitations of dependent claim 27. Therefore, Applicants respectfully submit that dependent claim 27 is patentable over Marnay for these additional reasons.

Erikson is cited for the disclosure of PEEK for use with vertebral implants. Although Erikson discloses generally the use of PEEK as a suitable material for manufacturing an implant, including bearing surfaces and articular surfaces, Erikson does not explicitly disclose the use of PEEK for *opposing* articulating surfaces, but merely states that the opposing articular surfaces should be selected to "minimize the amount of seizing which may occur during movement of the articular surfaces against one another." (Col. 5, lines 53-65). Instead, Erikson teaches away from using PEEK on opposing articulating surfaces that engage and slide against each other. Specifically, Erikson describes that the outer pieces be made of titanium or cobalt/chromium and the intermediate piece be made from plastic such as UHMW-PE or PEEK, or alternatively that all three pieces of the implant be made from cobalt/chromium. (See Col. 10, lines 1-12). Thus,

Erikson teaches that PEEK may be used as an articulation surface opposing a metal articulation surface, such as cobalt/chromium. However, Erikson fails to disclose or suggest *opposing* articulating surfaces made of PEEK. For this reason, applicants submit that claims 31-48 are allowable over the cited art.

Claim 33 as amended is further believed to be patentable over the combination of Marnay and Erikson because neither reference discloses or suggests smooth outer bearing surfaces that face and non-invasively engage with adjacent hard or connective tissue and extend along the entirety of each load bearing member such that each bearing member is allowed to slide along the adjacent hard or connective tissue. Both Marnay and Erikson disclose the use of bone engaging spikes or anchors to fix the implant to the endplates. Thus, the implants disclosed by the cited references are not allowed to slide along the adjacent hard or connective tissue. Thus, the cited art clearly does not teach, disclose or suggest all of the limitations of independent claim 33. Therefore, Applicants respectfully submit that dependent claim 33 is patentable over the combination of Marnay and Erikson. It follows that claims 34-41 which depend cognately therefrom, are believed to be allowable over the combination of Marnay and Erikson for the reasons mentioned above.

Similarly, Claim 42 is further believed to be patentable over the combination of Marnay and Erikson because neither reference discloses or suggests PEEK outer bearing surfaces having a smooth configuration for the entire extent thereof so as to lack any protrusions projecting outwardly therefrom for non-invasive sliding engagement with the corresponding natural end plates, or PEEK inner bearing surfaces of the matched PEEK load bearing members each having an arcuate configuration that cooperate to engage each other. Both Marnay and Erikson disclose the use of bone-engaging spikes or anchors on the outer bearing surfaces to fix the implant to the endplates. Further, Marnay and Erikson both disclose three piece implants, wherein only one of the outer bearing members has an arcuate inner bearing surface, while the central insert member comprises the mating arcuate bearing surface. Thus, the upper and lower bearing members of Marnay and Erikson do not both have PEEK inner bearing surfaces each having an arcuate

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configuration that cooperate to engage each other as required by the claim. Thus, the cited art clearly does not teach, disclose or suggest all of the limitations of independent claim 42. Therefore, Applicants respectfully submit that dependent claim 42 is patentable over the combination of Marnay and Erikson. It follows that claims 43-48 which depend cognately therefrom, are believed to be allowable over the combination of Marnay and Erikson for the reasons mentioned above.

As discussed above, the relied upon art does not disclose or suggest all of the limitations of independent claims 1, 33, or 42. Therefore, claims 1, 33 and 42, as well as claims 3, 21-28, 31, 34-41, 43-48 and 52-54 which depend cognately therefrom, are believed to be allowable over the relied upon art. Based on the foregoing, reconsideration and allowance of claims 1, 3, 21-28, 31, 33-48 and 52-54 are respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required with respect to this communication, or credit any overpayment, to Deposit Account No. 06-1135.

Respectfully submitted,

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